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Honest, Open, Proud for adolescents with mental illness:

Pilot randomized controlled trial

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Abstract

Background: Due to public stigma or self-stigma and shame, many adolescents with mental illness (MI) struggle with the decision whether to disclose their MI to others. Both disclosure and non-disclosure are associated with risks and benefits. Honest, Open, Proud (HOP) is a peer-led group program that supports participants with disclosure decisions in order to reduce stigma's impact. Previously, HOP had only been evaluated among adults with MI.

Methods: This two-arm pilot randomized controlled trial included 98 adolescents with MI. Participants were randomly assigned to HOP and treatment as usual (TAU) or to TAU alone. Outcomes were assessed pre (T0/baseline), post (T1/after the HOP program) and at 3-week follow-up (T2/six weeks after T0). Primary endpoints were stigma stress at T1 and quality of life at T2. Secondary outcomes included self-stigma, disclosure-related distress, empowerment, help-seeking intentions, recovery, and depressive symptoms. The trial is registered on ClinicalTrials (NCT02751229; http://www.clinicaltrials.gov).

Results: Compared to TAU, adolescents in the HOP program showed significantly reduced stigma stress at T1 ($d=0.92$, $p<.001$) and increased quality of life at T2 ($d=0.60$, $p=.004$). In a longitudinal mediation model, the latter effect was fully mediated by stigma stress reduction at T1. HOP further showed significant positive effects on self-stigma, disclosure-related distress, secrecy, help-seeking intentions, attitudes to disclosure, recovery and depressive symptoms. Effects at T1 remained stable or improved further at follow-up. In a limited economic evaluation HOP was cost-efficient in relation to gains in quality of life.

Conclusions: As HOP is a compact three-session program and showed positive effects on stigma and disclosure variables as well as on symptoms and quality of life, it could help to reduce stigma's negative impact among adolescents with MI.

Keywords: Randomized controlled trial; adolescents; mental illness; Honest, Open, Proud; Coming Out Proud; disclosure; secrecy

Abbreviations: HOP - Honest, Open, Proud; MI - Mental illness

Introduction

Adolescents with mental illness (MI) often experience stigma and discrimination which can have a severe impact on long-term clinical, social and vocational functioning (Kaushik, Kostaki, & Kyriakopoulos, 2016; Patel, Flisher, Hetrick, & McGorry, 2007). Unlike other stigmatized characteristics, MI is often invisible. Therefore many adolescents with MI struggle with the decision whether to disclose their condition to others. Disclosure may lead to labeling and discrimination, on the other hand it can offer opportunities for social support, facilitate help-seeking, increase authenticity and decrease the stress associated with secrecy (Pachankis, 2007). Given the consequences and irreversibility of disclosure, this can be a challenging decision and individuals may weigh the pros and cons differently. Honest, Open, Proud (HOP) is a peer-led group program that supports participants with MI in their disclosure decisions. HOP has so far only been evaluated in two RCTs among adults with MI (Corrigan et al., 2015; Rüsch, Abbruzzese et al., 2014), and both showed positive effects on stigma-related stress.

The concept of stigma stress is based on stress-coping models of stigma (Lazarus & Folkman, 1984). It occurs when stigmatized individuals feel that stigma-related harm exceeds their coping resources (Rüsch et al., 2009). If, on the other hand, people feel confident to cope with stigma, their level of stigma stress will be low. As disclosure decisions as well as stigma itself can be stressful and HOP supports participants in these domains, stigma stress is a plausible proximal outcome of HOP as evidenced by the above-mentioned RCTs. Non-interventional studies among adolescents and adults with MI showed consistent negative associations of stigma stress with quality of life and other aspects of well-being (Rüsch, Müller, Heekeren et al., 2014; Rüsch, Müller, Lay et al., 2014). We therefore expected that stigma stress reductions would lead to improved quality of life over time as a distal outcome.

We conducted this pilot RCT to examine HOP's efficacy to reduce the impact of mental illness stigma on adolescents with MI and investigated the economic impact of the

program in relation to mental health service use and quality of life outcomes. As two primary outcomes, compared to the control group we expected HOP to reduce short-term stigma stress after the 3-week program (T1); and to improve mid-term quality of life after the 3-week follow-up period (T2). As secondary outcomes, we expected improvements in other stigma- and disclosure-related and clinical outcomes after the intervention and at follow-up.

Methods

Trial design and participants

In this two-arm 1:1-RCT, participants were randomly assigned to HOP, combined with treatment as usual (TAU), or to a control group that received only TAU. Participants were recruited from three Departments of Child and Adolescent Psychiatry (Ulm, Augsburg, Ravensburg-Weissenau) in southern Germany between May 2016 and February 2017. All departments had inpatient wards, day clinics and outpatient clinics. As the recruitment of participants from the three outpatient clinics was not sufficient, an independent child and adolescent psychiatry outpatient practice in Ulm was added as recruitment site. This practice treats adolescents comparable in illness severity and sociodemographic variables to other outpatient settings and mainly with attention deficit, conduct, anxiety or affective disorders. About one in four has a history of psychiatric inpatient treatment and access does not depend on the type of health insurance.

Inclusion criteria for all participants were: at least one self-reported current axis-I or axis-II disorder according to ICD-10 (WHO, 2010) in response to a list of major diagnostic categories; age 13 to 18; ability to provide written informed consent; fluent German language skills; and at least a moderate level of self-reported disclosure-related distress (≥4 for ‘In general, how distressed or worried are you in terms of secrecy or disclosure of your mental illness to others?’, rated from 1/not at all to 7/very much). Exclusion criteria were intellectual disability; organic disorder; or diagnosis of only a substance- or alcohol-related disorder,

without non-substance related current psychiatric comorbidity, since disclosure of these disorders is not a topic specifically discussed in the HOP program. The trial was approved by the ethics committees of Ulm University and of the regional college of physicians. Parents or legal guardians as well as adolescents provided written informed consent after being fully informed about study procedures. Before including the first participants, the trial was registered on ClinicalTrials (NCT02751229; www.clinicaltrials.gov).

Sample size

Prior to this study, there were neither data on HOP's efficacy among adolescents nor data on HOP in inpatient settings. Furthermore, the HOP version for adolescents differs from the program for adults that was evaluated in previous RCTs. Based on a power of 80% to detect an effect on at least one endpoint, alphas of 0.025, and two primary endpoints with an expected correlation of r=-0.3 (unpublished data), 100 participants were sufficient to detect medium effect sizes of d=0.5 on stigma stress, similar to effects on stigma stress in a previous adult HOP RCT (Rüsch, Abbruzzese et al., 2014), and d=0.4 on quality of life.

Randomization

After completing the baseline assessment (T0), participants were randomly assigned to the intervention (HOP+TAU) or the control group (TAU alone) by block randomization separately for each study center. Randomization lists and closed envelopes were generated by the Institute of Epidemiology and Medical Biometry, University of Ulm, Germany. Blinding of participants was not feasible, and research staff were not blinded as outcomes were assessed by self-report. To reduce the risk of contamination between trial arms, HOP participants were asked not to share HOP materials with control group participants.

HOP Intervention

HOP's goal is to support participants with the decision whether to disclose their MI in different settings. HOP was developed by Corrigan and colleagues based on a previous book (Corrigan & Lundin, 2001). It was previously known as 'Coming Out Proud' and is now called 'Honest Open Proud' (www.comingoutproudprogram.org). Originally it was developed for adults with MI. Sue McKenzie, Suzette Urbashich, WISE Wisconsin (https://wisewisconsin.org/), and Patrick W. Corrigan adapted HOP for adolescents with MI in the US. Following consultations with German peers and service users and based on the results of our focus group study among German adolescents with MI on disclosure (Mulfinger et al, submitted for publication), we translated and adapted the HOP adolescent version for the German context and added vignettes about disclosure and social media.

As disclosure decisions depend on the setting and are very individual, HOP discusses levels of disclosure, settings of disclosure and how to choose persons to disclose to. It is not HOP's aim to push participants towards disclosure, but to empower them to make their own decision. HOP is a peer-led group program that covers five themes; (i) Beliefs: Starting with stories of adolescents in the workbook, participants explore attitudes about having a MI and ways to challenge self-stigmatizing beliefs; (ii) Pros and Cons of Disclosure: Participants discuss short-term and long-term risks and benefits of (non-)disclosure in different settings, levels of disclosure and disclosure via social media; (iii) The right person: Participants learn how to find people that are good to disclose to and how to test them out before a potential disclosure, anticipating responses of others to one's disclosure; (iv) Telling one's story: After reading first-person accounts in the workbook, participants practice how to tell their story, if they decide to do so, and how to identify peers who could support them; and (v) the role of solidarity and peer support, a summary of lessons learnt during the program and next steps. Lessons are structured by vignettes, first-person accounts, worksheets, tables and role plays.

HOP was conducted in three two-hour sessions during a three-week period. In previous HOP RCTs among adults with MI, two peers with lived experience of MI facilitated the groups. Due to the adolescent participants and the predominantly inpatient setting in this study, groups were facilitated by a young adult peer with lived experience of MI and a young mental health professional. Before recruitment onset, peer and professional group facilitators attended a HOP training conducted by NR and NM. Prior to the RCT, all facilitators ran at least one HOP practice group. Manual fidelity in the practice groups was >80%.

Fidelity

In order to check manual fidelity, a checklist covering the HOP workbook content was adapted from a previously used HOP fidelity scale (Rüsch, Abbruzzese et al., 2014). One research assistant was present in every session and completed the fidelity checklist. Fidelity was high with 87-98% for lesson one, 86-97% for lesson two, and 79-85% for lesson three. Mean fidelity across sessions and sites was 89%.

Measures

Outcomes were measured at three timepoints: baseline (Pre/T0); immediately following the intervention, or three weeks after baseline for TAU-only participants (Post/T1); and 6 weeks after baseline (Follow-up/T2). We assessed two primary endpoints as defined a priori in the study protocol: Stigma stress reduction as proximal outcome at T1, and quality of life as distal outcome at T2. Stigma-stress was assessed by the 8-item Stigma Stress Scale (Rüsch et al., 2009). Four items measured the primary appraisal of stigma as harmful (alphas in our study 0.90/0.93/0.92 for T0/T1/T2) and four items the secondary appraisal of perceived resources to cope with stigma-related harm (alphas 0.70/0.77/0.89). All items were rated from 1 to 7, higher mean scores indicating more harm or more coping resources. A stigma stress score was computed by subtracting perceived resources from perceived harm, with higher difference

scores (range -6 to +6) indicating more stigma-stress. Health-related quality of life was measured with the KIDSCREEN-10 index (Ravens-Sieberer et al., 2010), with higher sum scores (range 10 to 50) indicating better quality of life (alphas 0.80/0.85/0.79).

Secondary outcomes included empowerment as measured by the 9-item Self-Esteem and the 4-item Optimism subscales of the Empowerment Scale (Rogers, Chamberlin, Ellison, & Crean, 1997), with higher mean scores from 1 to 4 indicating stronger empowerment (alphas 0.91/0.93/0.91 and 0.56/0.73/0.77). Disclosure-related distress was examined by the above-mentioned screening item (Rüsch, Abbruzzese et al., 2014). Two items assessed attitudes towards disclosure in one's personal or educational/professional environment, respectively ('In general, how comfortable would you feel talking to a friend or family member [item 1; '... to a teacher or employer ...' in item 2] about your mental health, for example, telling them you have a mental health diagnosis and how it affects you?', from 1/not at all to 7/very much). Hopelessness was examined with the 4-item brief version of Beck's Hopelessness Scale (Yip & Cheung, 2006), with higher sum scores from 4 to 24 equaling more hopelessness (alphas 0.85/0.81/0.78). Self-stigma was assessed by two measures. First, the 10-item Internalized Stigma of Mental Illness Inventory-Short Form (ISMI; Boyd, Otilingam, & Deforge, 2014) is a broad measure that includes experienced discrimination and social withdrawal, with higher mean scores between 1 and 4 indicating more self-stigma (alphas 0.80/0.76/0.80). Second, the 5-item self-concurrence/apply subscale of the Self-Stigma of Mental Illness Scale-Short Form (SSMIS; Corrigan et al., 2012) assessed whether respondents applied negative stereotypes to themselves (alphas 0.70/0.75/0.81), higher sum scores from 5 to 45 equaling more self-stigma.

Participants reported intentions to seek help for mental health problems from different sources in the General Help Seeking Questionnaire (Wilson, Deane, Ciarrochi, & Rickwood, 2005), from 1/extremely unlikely to 7/extremely likely. Based on a factor analysis of help-seeking intentions in an unrelated study (Waldmann et al., in preparation), we averaged

intentions to seek help from family/friends (items 1-4) and from professionals (items 5, 7, 10). Recovery was examined by the 4-item Self-Identified Stage of Recovery Scale (Andresen, Caputi, & Oades, 2010), higher sum scores from 4 to 24 indicating better recovery (alphas 0.74/0.75/0.73). Secrecy and social withdrawal were assessed using Link's Stigma Coping Orientation Scales (Link, Mirotznik, & Cullen, 1991), with higher mean scores from 1 to 6 equaling more secrecy or withdrawal (alphas for 5 secrecy items 0.64/0.72/0.81; for 7 social withdrawal items 0.74/0.77/0.74). Depressive symptoms were assessed using the 15-item German version of the Center for Epidemiologic Studies-Depression Scale (Meyer & Hautzinger, 2001), with higher sum scores (range 0 to 45) indicating more depressive symptoms (alphas 0.83/0.83/0.83). At T1, HOP participants responded to an open-ended question what they liked or disliked about HOP and themes were summarized.

Statistical analyses

Baseline characteristics of dropouts (n=22) versus completers (n=76) after six weeks were compared using t-tests or chi-square tests. We analyzed intervention effects first by intention-to-treat (ITT) analysis and a linear mixed model for repeated measures (MMRM; Ashbeck & Bell, 2016; Davis, 2014); and second by available case analysis using ANCOVAs. With two primary endpoints, we corrected the significance level for both to $p<0.025$. All other analyses were exploratory with $p<0.05$.

Our MMRM analysis used a restricted maximum likelihood (REML)-based repeated-measures approach. The analyses included the fixed, categorical effects of group, time point of measurement, and group-by-timepoint interaction as well as the fixed covariates of baseline score and center. An unstructured (co)variance structure shared across treatment groups was used to model the within-patient errors. The Kenward-Roger approximation was used to estimate denominator degrees of freedom and adjust standard errors. Analyses were

implemented with SAS PROC MIXED. Effect size d was calculated by dividing MMRM estimated group differences by the pooled standard deviation at baseline for each outcome.

For ANCOVAs we used all available data which is more conservative than a per-protocol analysis because participants who had been randomized to HOP but had not participated in all sessions were included (Figure 1). Intervention effects were tested using group as between- and time as within-subject factors; the baseline value of the respective outcome and center/site were used as covariates. Effect size estimates are provided as partial η^2, with η^2 of 0.10 or 0.25 indicating medium or large effect sizes (Vacha-Haase & Thompson, 2004).

The hypothesized longitudinal mediation model of intervention effects on the two primary endpoints was tested using structural equation modeling within R version 3.3.3 (lavaan library; Figure 2). Changes in stigma stress from Pre/T0 to Post/T1 (T0-T1, difference scores >0 indicating decreased stigma stress) as well as changes in quality of life from T0 to T2 (T2-T0, differences >0 indicating increased quality of life) were calculated. Missing data were accounted for by Full Information Maximum Likelihood estimation, and bootstrapping ensured robust standard errors (bootstrap replications=1000).

To contextualize HOP outcomes in relation to program costs, we performed a limited threshold analysis, first to estimate the value of mental health service use which would need to be reduced for HOP to be economically efficient from a healthcare perspective and second to contextualize the quality of life outcomes. We estimated Quality Adjusted Life Years (QALYs) by mapping the KIDSCREEN-10 responses onto CHU9D utility scores using the algorithm recommended by Chen and colleagues (2014).

Results

Recruitment, assessment and baseline characteristics

In total, we contacted 160 participants of whom 98 were included and randomized. With a

low refusal rate, adolescents were mainly excluded due to low disclosure-related distress or lack of parental consent (Figure 1). Recruitment ended when the approximate planned sample size was reached. There were no significant group differences between the HOP and control groups at baseline (Table 1; all p-values >.35). All participants completed questionnaires at baseline (T0), 84 (86 %) completed the post assessment (T1) and 76 participants (78 %) the follow-up assessment (T2). Baseline characteristics of the 22 participants lost to follow-up did not differ significantly from the 76 completers (Online Table 1). Recruitment from the outpatient practice proved more difficult than expected, as many potential outpatient participants did not report sufficient disclosure-related distress. Altogether, we included 85 participants from inpatient settings (44 in the HOP, 41 in the control condition), 7 from hospital day-clinics, and 6 from the independent outpatient practice. No adverse events occurred among HOP or TAU participants.

-- Insert Tables 1 and 2 and Figure 1 about here –

Primary outcomes

In the MMRM analysis, we found significant HOP effects with a large effect size on the proximal primary endpoint of stigma stress after 3 weeks/T1 (Table 2). Stigma stress continued to decrease among HOP participants at follow-up. With respect to our distal primary endpoint, we found a significant positive HOP effect on quality of life at follow-up/T2 with a medium effect size. Results were very similar in the ANCOVAs (Online Table 2).

Secondary outcomes

In terms of secondary outcomes (Table 2) we found significant and positive HOP effects on self-stigma both at T1 (at a trend-level for the ISMI scale) and at T2, with effect sizes

increasing from small to medium during follow-up. There were small, marginally significant short-term effects on empowerment in terms of self-esteem and optimism at T1 that lost significance at T2. Disclosure-related distress and secrecy were significantly reduced among HOP participants, with medium effect sizes at T1 and large effect sizes at T2. Social withdrawal decreased in the HOP group at T1. Intentions to seek help in one's private environment or from healthcare professionals increased significantly in the HOP group at T1 and remained significantly increased at T2 for professional help. HOP significantly reduced hopelessness at T2 in the available-case ANCOVA (Online Table 2) and at a trend level in MMRM (Table 2). Attitudes towards disclosure among family/friends and in school or employment settings improved significantly among HOP group participants at T1 and T2. There was a small-to-medium effect on recovery at T2 among HOP participants. Finally, HOP had a large effect on depressive symptoms at T2.

-- Insert Figure 2 about here –

Mediation analysis of intervention and both primary endpoints

In the path model estimated by structural equation modeling, the positive association between the HOP program and increased quality of life at follow-up (T2) was fully mediated by decreased stigma stress after the intervention (T1; Figure 2). Due to estimating a saturated model (df=0), model fit could not be interpreted.

Limited economic evaluation

Costs for delivering HOP were estimated and included training peers and professionals, time for peers and professionals to deliver HOP, costs for printing training and HOP materials and venue hire. If we are very conservative and include the cost of training facilitators in addition to delivering HOP, program costs are estimated to be €154 per participant (€70 per participant

if excluding training and set up costs). Although representative data on costs of mental health service use for young people do not exist in Germany, we know from data in Britain that average annual costs associated with mental health service use for young people aged 5-15 are €1,697 when inflated to 2016 levels (Snell et al 2013). Given that health service utilization and spending tend to be higher in Germany compared to England (http://www.oecd.org/els/health-systems/health-data.htm), if one were aiming for neutrality in terms of treatment costs, HOP would be justified from the perspective of the health system if it were just to reduce a fraction of mental health service use. We could also contextualize the value of improved quality of life given that HOP also demonstrated an improvement in quality of life. Even if we were to include the costs of training HOP facilitators, relative to TAU, the utility gains of 0.044 points for those who received HOP vs TAU at T2 would translate to €20,533/QALY if the gains were only to last for 2 months and to €6,969/QALY if the gains were to last for 6 months - a reasonable investment given the standard National Institute for Clinical Excellence threshold value of £20,000-£30,000 (€25,552 - €38,828).

Participants' views

Peer group facilitators were seen as inspiring role models. Participants liked to learn about other participants' disclosure decisions and to hear their stories. They thought HOP improved their knowledge about disclosure and valued the clear structure of the workbook and its realistic scenarios. Participants liked the hands-on strategies how to talk about their MI and how to seek out persons to disclose to. Some felt relieved when talking about their MI in the safe group space. Participants highlighted the group interaction which was characterized by openness, trust and respect. Some felt the first module was too theoretical and demanding, others found it hard to concentrate or thought some material was too detailed.

Discussion

Our findings support the feasibility, efficacy and cost-effectiveness of HOP for adolescents. While the rhythms of hospital wards offered a challenge, including the early discharge of some participants, dropout rates remained moderate. Our hypothesis that HOP would improve stigma stress, as a proximal outcome after the intervention, and that this would lead to improved quality of life at follow-up was supported. HOP also led to significant improvements across a broad range of outcomes, including self-stigma, disclosure variables, help-seeking intentions and depressive symptoms. We also observed weaker positive effects on recovery and empowerment. This is promising and suggests that HOP can improve clinical and social outcomes when added to standard care. The three-session HOP program could be a useful, cost-efficient and practical intervention as it is brief and can be delivered in a variety of settings.

This study has some implications for research and practice. Future studies should examine HOP's feasibility and efficacy in different settings as well as HOP's effect on actual disclosure decisions and the effects of these decisions on participants over time. As there are other interventions to reduce self-stigma, including narrative, psychoeducational and acceptance-based approaches (Tsang et al., 2016), future work should compare their efficacy among young people. Our findings suggest stronger HOP effects in this age group compared to previous RCTs among adults (Corrigan et al., 2015; Rüsch, Abbruzzese et al., 2014). Several explanations are possible and could be examined in future research: Young people may be more open to discuss and change their views on disclosure; they might be more optimistic to deal successfully with stigma; and they may have a larger social network than adults with a long history of MI and thus have better opportunities to test, practice and evaluate disclosure-related choices. Therefore interventions to reduce stigma's impact may be particularly worthwhile in the early course of the illness (Gronholm et al., 2016). This is in line with a public health perspective that underlines the negative consequences of stigma for

adolescent mental health (Kaushik, Kostaki, & Kyriakopoulos, 2016) and the scarcity of appropriate interventions for this target group (Patel et al., 2007).

Limitations

Participants in our study were mainly recruited from inpatient settings and from only one independent outpatient practice which limits generalizability and conclusions about HOP in outpatient settings. Only a minority of approximately one in four outpatients appeared to be significantly distressed by disclosure decisions. Future HOP studies could examine its efficacy for that group and might consider a lower disclosure distress threshold. The three-week follow-up period was brief and long-term effects remain unclear. Likewise the efficacy of a booster session to maintain short- and mid-term effects should be examined in future studies. We cannot rule out contamination between trial arms. Research staff were not blinded to group allocation. Although we collected data on intervention costs, the economic analysis is limited as we did not have cost data beyond intervention delivery. Future research should measure the impact of HOP on health service use, as reduced symptoms could lead to reduced service use while increased help-seeking intentions could lead to increased service use. Reduced stigma stress and increased help-seeking from friends/peers and family may also impact social relationships and educational performance; costs associated with these outcomes could also be considered in future studies in addition to the potential for HOP to increase participants' confidence in seeking future employment or other opportunities associated with potential economic impact.

Conclusions

If our findings are corroborated by future research, HOP can support adolescents with MI in their disclosure decisions and help them cope with stigma and discrimination. HOP has the potential to improve clinical outcomes as well as the recovery and well-being of adolescents.

Key points

- Adolescents with mental illness (MI) may decide to conceal their condition in order to avoid stigma and discrimination.
- Honest, Open, Proud (HOP) is a manualized peer-led group program that supports participants with MI with disclosure decisions in order to reduce stigma's impact.
- HOP for adolescents appears to be a safe, feasible and cost-efficient intervention for adolescents with MI that has significant positive effects on stigma-related stress, quality of life, self-stigma, disclosure-related distress, secrecy, help-seeking intentions, attitudes to disclosure, recovery and depressive symptoms.

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Figure 1. Flowchart of participants

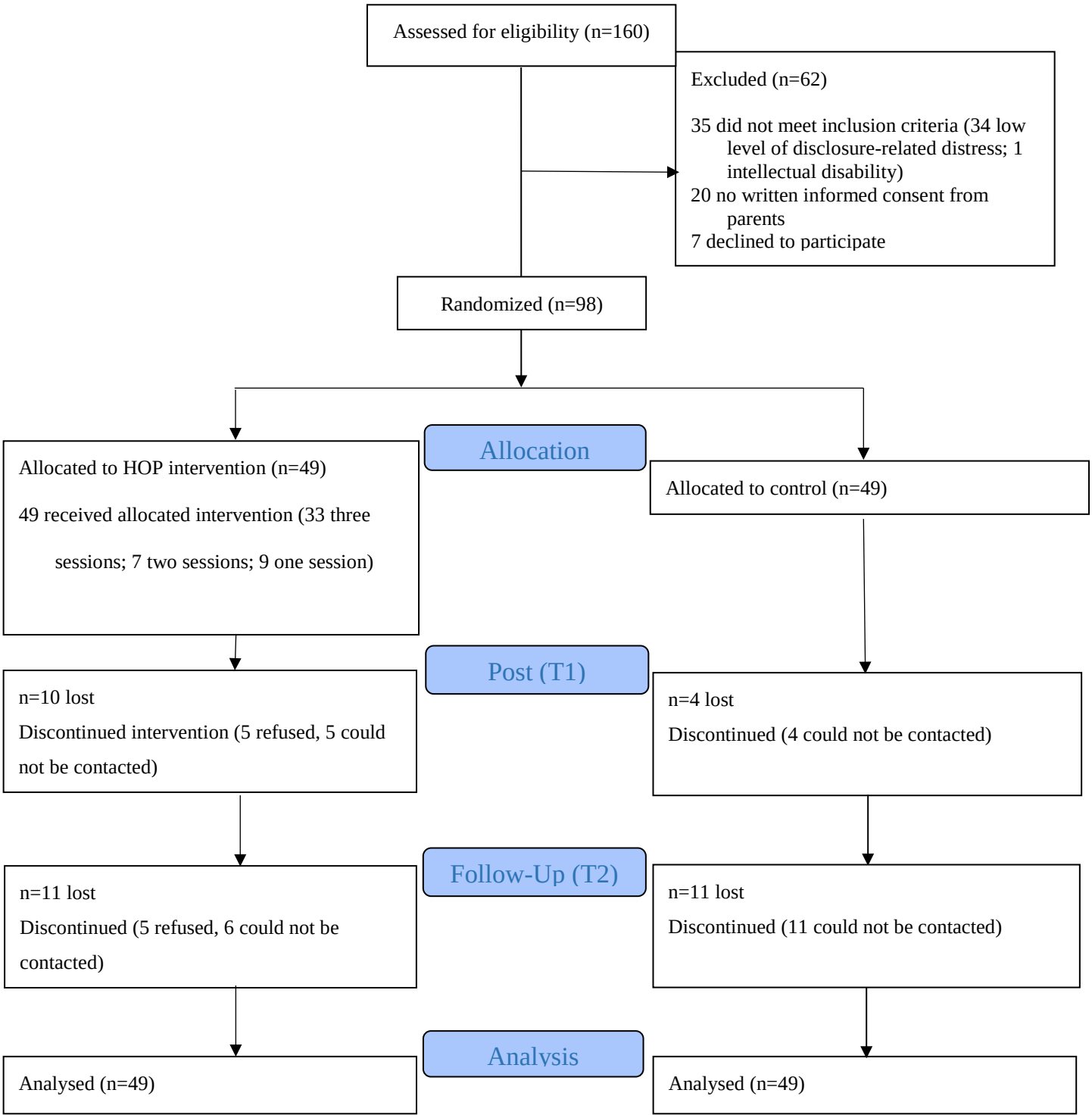

Figure 2. Longitudinal path model of intervention effect on quality of life at follow-up/T2, mediated by stigma stress reduction after the intervention/T1. Structural equation modeling with standardized coefficients, N=98, indirect (mediated) effect 0.17, p=.03; total effect 0.30, p=.01; * p<0.05, ***p<0.001

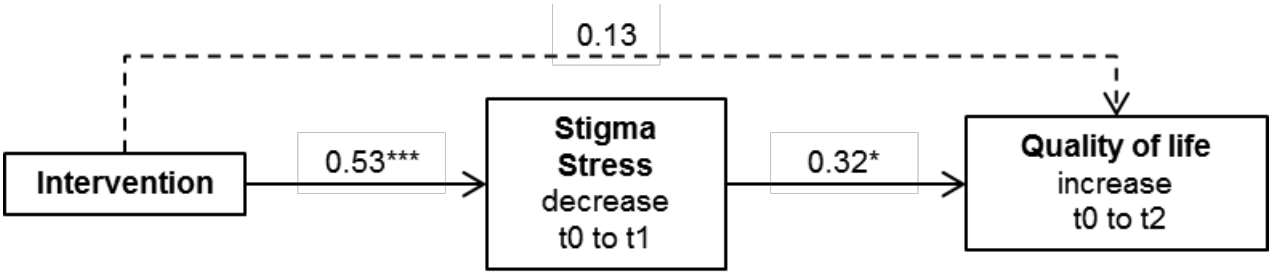

Table 1. Baseline characteristics of participants (HOP, n=49, versus Control group, n=49)

	HOP M (SD) or n (%)	Control M (SD) or n (%)
Sociodemographic variables		
Age, years	15.8 (1.2)	15.7 (1.1)
Female	33 (67 %)	35 (71 %)
Born in Germany	47 (96 %)	46 (94 %)
Clinical and diagnostic variables		
Number of psychiatric inpatient treatments (incl. current for inpatient participants)	1.5 (1.2), Median 1, range 0 - 5	1.7 (1.6) Median 1, range 0 – 10
Months since first diagnosis	21.5 (32.4) Median 9, range 0.5 - 144	23.5 (32.3) Median 12, range 1 - 132
Depressive Disorder	30 (64 %)	28 (58 %)
Anxiety Disorder	9 (19 %)	8 (17 %)

Table 2. Mixed model for repeated measures (MMRM, bold for primary endpoints). Positive group differences indicate an increase of the respective outcome in the HOP group as compared to the control condition, and vice versa for negative estimates. For means and SD of available cases at T0, T1 and T2 see Online Table 2.

	Estimated group differences: M (95%-CI)		T1 (post)			T2 (follow-up)		
	Post (T1)	Follow-up (T2)	T	d	p	T	d	p
Stigma Stress [a]	**-2.06 (-2.70 – -1.42)**	-2.16 (-2.89 – -1.43)	**-6.41**	**0.92**	**<.001**	-5.89	0.96	<.001
Quality of Life [b]	0.82 (-1.34 – 2.98)	**3.54 (1.14 – 5.93)**	0.75	0.14	0.45	**2.94**	**0.60**	**0.004**
Self-Stigma (ISMI) [c]	-0.16 (-0.33 – 0.01)	-0.35 (-0.54 – -0.16)	-1.92	0.28	0.058	-3.61	0.61	<.001
Self-Stigma (SSMIS) [d]	-2.93 (-5.35 – -0.52)	-5.14 (-8.22 – -2.05)	-2.42	0.36	0.018	-3.32	0.63	0.001
Empowerment/Self-esteem [e]	0.21 (0.04 – 0.39)	0.19 (-0.03 – 0.41)	2.43	0.29	0.017	1.71	0.26	0.09
Empowerment/Optimism [e]	0.20 (0 – 0.40)	0.21 (-0.03 – 0.46)	1.95	0.33	0.055	1.71	0.35	0.09
Disclosure-related distress	-0.87 (-1.37 – -0.37)	-1.18 (-1.85 – -0.51)	-3.45	0.53	<.001	-3.51	0.71	<.001
Secrecy [f]	-0.44 (-0.79 – -0.08)	-0.78 (-1.16 – -0.40)	-2.44	0.46	0.016	-4.07	0.81	<.001
Social withdrawal [f]	-0.34 (-0.63 – -0.05)	-0.29 (-0.66 – 0.08)	-2.31	0.34	0.023	-1.55	0.29	0.12

Help-seeking (family/friends) [g]	0.77 (0.36 – 1.17)	0.48 (-0.02 – 0.98)	3.79	0.55	<.001	1.93	0.34	0.057
Help-seeking (professional) [g]	0.60 (0.15 – 1.05)	0.82 (0.32 – 1.32)	2.64	0.47	0.010	3.26	0.64	0.002
Hopelessness [h]	-0.51 (-1.88 – 0.85)	-1.22 (-2.68 – 0.24)	-0.75	0.10	0.46	-1.66	0.23	0.10
Attitudes to disclosure (to family/friends)	1.00 (0.43 – 1.57)	1.02 (0.43 – 1.61)	3.52	0.62	<.001	3.43	0.64	0.001
Attitudes to disclosure (to teacher/employer)	0.66 (0.15 – 1.16)	0.91 (0.28 – 1.53)	2.59	0.46	0.011	2.88	0.64	0.005
Stage of recovery [i]	0.15 (-1.34 – 1.64)	1.59 (0.10 – 3.07)	0.20	0.03	0.85	2.13	0.35	0.037
Depressive symptoms [j]	-1.25 (-4.87 – 2.38)	-7.25 (-10.85 – -3.65)	-0.68	0.12	0.50	-4.00	0.72	<0.001

[a] Stigma Stress Scale (Rüsch et al., 2009); [b] KIDSCREEN-10 Index (Ravens-Sieberer et al., 2010); [c] Internalized Stigma of Mental Illness Inventory, Short Form (Boyd et al., 2014); [d] Self-Stigma of Mental Illness Scale-Short Form, subscale apply/self-concurrence (Corrigan et al., 2012); [e] Empowerment Scale (Rogers et al., 1997); [f] Stigma Coping Orientation Scales (Link et al., 1991); [g] General Help Seeking Questionnaire (Wilson et al., 2005); [h] Beck Hopelessness Scale, Short Version (Yip & Cheung, 2006); [i] Self-Identified Stage of Recovery Scale (Andresen et al., 2010); [j] Center for Epidemiologic Studies Depression Scale (Meyer & Hautzinger, 2001)

Online Table 1. Baseline/T0 characteristics of completers vs. dropouts

	Completers (at T2, n=76) M (SD) or n (%)	Dropouts (at T2, n=22) M (SD) or n (%)	T	χ^2	p
Sociodemographic variables					
Age, years	15.7 (1.1)	15.8 (1.4)	0.33		0.74
Female	54 (71 %)	14 (64 %)		0.44	0.51
Born in Germany	73 (96 %)	20 (91 %)		0.93	0.33
Clinical variables					
Depressive symptoms [a]	26.1 (9.9)	23.9 (10.6)	-0.90		0.37
Number of psychiatric inpatient treatments (incl. current)	1.6 (1.5)	1.6 (1.2)	0.08		0.94
Months since first diagnosis	22.6 (32.3)	22.2 (32.5)	-0.05		0.96
Depressive Disorder	49 (65 %)	9 (41 %)		1.87	0.17
Anxiety Disorder	15 (20 %)	2 (11 %)		0.88	0.35
Disclosure variables					
Attitudes to disclosure (teacher/employer)	2.1 (1.4)	2.3 (1.6)	0.52		0.61
Attitudes to disclosure (family/friends)	2.9 (1.6)	3.1 (1.8)	0.49		0.62
Disclosure-related distress [b]	4.8 (1.6)	4.1 (1.8)	-1.70		0.09

[a] Center for Epidemiologic Studies-Depression Scale (Meyer & Hautzinger, 2001)

[b] 'In general, how distressed or worried are you with respect to secrecy or disclosure of your mental illness to others?', rated from 1/not at all to 7/very much

Online Table 2. ANCOVAs for HOP and control groups (baseline score of each outcome and center as covariates; primary endpoints in bold print)

							T1			T2		
		Baseline/T0 M (SD)	Post/T1 M (SD)	Group difference T1 M (95%-CI)	Follow-up/T2 M (SD)	Group difference T2 M (95%-CI)	F	partial η^2	*p*	F	partial η^2	*p*
Stigma Stress [a]	HOP	-0.07 (2.37)	**-2.33 (1.91)**	**-2.04**	-2.56 (1.95)	-2.28	**41.7**	**0.34**	**<.001**	33.9	0.32	<.001
	Control	-0.35 (2.13)	**-0.29 (2.01)**	**(-2.89 – -1.18)**	-0.28 (2.09)	(-3.20 – -1.35)						
Quality of Life [b]	HOP	28.97 (5.95)	30.32 (7.37)	1.36	**32.97 (5.92)**	**4.17**	0.7	0.01	0.40	**9.7**	**0.12**	**0.003**
	Control	28.92 (5.83)	28.97 (6.92)	(-1.75 – 4.46)	**28.80 (6.34)**	**(1.33 – 7.01)**						
Self-Stigma (ISMI) [c]	HOP	2.38 (0.62)	2.18 (0.56)	-0.14	2.04 (0.48)	-0.29	4.3	0.05	0.040	10.9	0.13	0.001
	Control	2.30 (0.54)	2.32 (0.48)	(-0.37 – 0.08)	2.33 (0.57)	(-0.53 – -0.05)						
Self-Stigma (SSMIS) [d]	HOP	21.57 (8.58)	17.09 (7.43)	-3.02	15.16 (7.37)	-5.05	6.6	0.08	0.012	11.1	0.13	0.001
	Control	20.63 (7.64)	20.11 (8.75)	(-6.58 – 0.53)	20.21 (10.23)	(-9.14 – -0.97)						
Empowerment/ Self-esteem [e]	HOP	2.33 (0.78)	2.61 (0.76)	0.28	2.69 (0.61)	0.27	6.6	0.08	0.012	2.6	0.03	0.11
	Control	2.31 (0.66)	2.33 (0.70)	(-0.04 – 0.60)	2.43 (0.70)	(-0.03 – 0.57)						
Empowerment/ Optimism [e]	HOP	2.43 (0.60)	2.65 (0.62)	0.19	2.70 (0.62)	0.19	4.6	0.05	0.036	2.1	0.03	0.16
	Control	2.49 (0.60)	2.46 (0.69)	(-0.10 – 0.47)	2.51 (0.77)	(-0.13 – 0.51)						
Disclosure-related distress	HOP	4.70 (1.65)	3.92 (1.20)	-0.86	3.43 (1.53)	-1.30	11.8	0.13	0.001	14.4	0.17	<.001
	Control	4.61 (1.68)	4.78 (1.44)	(-1.44 – -0.27)	4.74 (1.41)	(-1.97 – -0.63)						
Secrecy [f]	HOP	3.74 (0.83)	3.31 (0.85)	-0.54	3.15 (0.96)	-0.86	6.3	0.07	0.014	16.0	0.18	<.001
	Control	3.78 (1.09)	3.86 (1.12)	(-0.98 – -0.11)	4.01 (1.02)	(-1.32 – -0.41)						
Social withdrawal [f]	HOP	4.04 (0.91)	3.71 (0.98)	-0.44	3.70 (0.94)	-0.48	5.9	0.07	0.017	3.1	0.04	0.09
	Control	4.04 (1.09)	4.14 (1.03)	(-0.88 – 0.00)	4.17 (1.05)	(-0.93 – -0.02)						

Help-seeking (family/friends) [g]	HOP	3.44 (1.36)	4.28 (1.32)	0.97	4.17 (1.32)	0.82	14.5	0.15	<.001	5.5	0.07	0.022
	Control	3.30 (1.45)	3.31 (1.39)	(0.37 – 1.56)	3.35 (1.40)	(0.20 – 1.45)						
Help-seeking (professional) [g]	HOP	3.59 (1.31)	4.37 (1.15)	0.72	4.61 (1.12)	0.97	8.6	0.10	0.004	11.7	0.14	0.001
	Control	3.63 (1.28)	3.65 (1.40)	(0.16 – 1.28)	3.63 (1.41)	(0.39 – 1.55)						
Hopelessness [h]	HOP	14.42 (5.32)	13.18 (4.51)	-1.21	11.74 (3.83)	-2.21	0.5	0.01	0.48	4.2	0.06	0.043
	Control	14.82 (5.11)	14.39 (4.81)	(-3.24 – 0.82)	13.95 (4.78)	(-4.19 – -0.23)						
Attitudes to disclosure (to family/friends)	HOP	3.10 (1.62)	4.21 (1.40)	1.21	4.13 (1.44)	1.32	12.3	0.13	0.001	10.8	0.13	0.002
	Control	2.83 (1.59)	3.00 (1.61)	(0.55 – 1.87)	2.82 (1.56)	(0.63 – 2.00)						
Attitudes to disclosure (to teacher/employer)	HOP	2.00 (1.24)	2.60 (1.33)	0.60	2.86 (1.52)	0.91	7.0	0.08	0.010	9.6	0.12	0.003
	Control	2.27 (1.58)	2.00 (1.13)	(0.06 – 1.14)	1.95 (1.25)	(0.27 – 1.54)						
Stage of recovery [i]	HOP	14.64 (4.80)	15.48 (4.20)	0.46	16.67 (4.13)	1.94	0.1	0.002	0.72	3.6	0.05	0.06
	Control	14.92 (4.35)	15.02 (4.70)	(-1.49 – 2.40)	14.73 (4.29)	(0.00 – 3.88)						
Depressive symptoms [j]	HOP	26.22 (10.05)	22.28 (11.34)	-1.30	18.16 (10.27)	-6.55	0.6	0.01	0.43	14.0	0.16	<.001
	Control	24.92 (10.16)	23.58 (10.94)	(-6.14 – 3.55)	24.71 (11.24)	(-11.47 – -1.63)						

[a] Stigma Stress Scale (Rüsch et al., 2009); [b] KIDSCREEN-10 Index (Ravens-Sieberer et al., 2010); [c] Internalized Stigma of Mental Illness Inventory, Short Form (Boyd et al., 2014); [d] Self-Stigma of Mental Illness Scale-Short Form, subscale apply/self-concurrence (Corrigan et al., 2012); [e] Empowerment Scale (Rogers et al., 1997); [f] Stigma Coping Orientation Scales (Link et al., 1991); [g] General Help Seeking Questionnaire (Wilson et al., 2005); [h] Beck Hopelessness Scale, Short Version (Yip & Cheung, 2006); [i] Self-Identified Stage of Recovery Scale (Andresen et al., 2010); [j] Center for Epidemiologic Studies-Depression Scale (Meyer & Hautzinger, 2001)

Online Table 3. CONSORT checklist

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	4-5
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	5
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and	

		adjusted analyses	10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10-11 and Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4
	14b	Why the trial ended or was stopped	11
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13 f., Figure 2, Online Tables 1 and 2
Harms	19	All important harms or unintended effects in each group	11
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14
Other information			
Registration	23	Registration number and name of trial registry	2; 5
Protocol	24	Where the full trial protocol can be accessed, if available	2; 5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	16